REMARKS

Claims 1-5 and 8 – 10, and 12-15 are pending in the present application. Claims 6, 7, and 11 have been cancelled. Claims 1-15 are rejected.

Claims 1, 18-10, and 12 have been amended. The support for the amendments is found in the claims as filed.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

The Rejection Under 35 USC § 112, first paragraph

The Examiner has rejected Claims 1-15 under 35 USC § 112, first paragraph, as containing subject matter that was not described in the specification in such a way to enable one skilled in the art to which it pertains to make and/or use the invention. The Examiner states that the written disclosure of the specification enables only the method to treat SARS and dies not reasonably provide enablement for a method to prevent SARS. The Applicant has amended Claim 1 to reflect a method claim only to treatment and respectfully requests that the rejection be removed.

Rejection Under 35 USC §103(a) Over Gerber et al. US 2001/0044410 in view of Adams et al. US 2004/0077601

Claims 1-5 and 11-15 have been rejected under 35 USC 103(a) as being unpatentable over Gerber et al. US 2001/0044410 in view of Adams et al. US 2004/0077601. The Examiner states that Gerber et al. teaches a method and composition that treats a condition caused by an immune response to a virus. Further, the Examiner states that Geber et al. discloses a saline solution which is administered to the nasal mucosa that includes zinc acetate, zinc gluconate, zinc oxide, citric acid and ascorbic acid and gives the amount of the zinc gluconate that is administered and amount of ascorbic acid that is administered. The Examiner states that the pH of the composition is inherent in the disclosure since ascorbic acid has a pH of 3. Additionally, the Examiner sites Adams to show the teaching of a aerosol spray mucosally to the nose for SARS. Applicants respectfully traverse this rejection based on the remarks contained herein.

Gerber et al. discloses a composition that includes an effective amount of a pain relieving and anti-inflammatory pharmaceutical. Gerber fails to teach or suggest a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives and thermoreversible polymers; from about .001% to about 20% by weight of a sensate; and wherein the composition has a viscosity of from about 1 cps to about 2000 cps. The Examiner states that Example disclosed in paragraph 73 discloses the amount of zinc gluconate and ascorbic acid, however this example describes a composition administered in liquid form not a nasal composition.

Adams et al. discloses a method for treating a subject in need with the Formula I described in the specification in an amount to inhibit abnormal mammalian cell proliferation and thereby inhibit the condition. Additionally Adams, discloses a method for stimulating an immune response in a subject comprising administering an agent of Formula I and an antibody or antibody fragment. Adams does not teach or suggest a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives and thermoreversible polymers; from about .001% to about 20% by weight of a sensate; and wherein the composition has a viscosity of from about 1 cps to about 2000 cps. The Examiner states that Adams teaches an aerosol spray mucosally to the nose on page 40 and 41. However, on page 39, paragraph 0349 discloses that administration by inhalation is for lung tumors. The disclosure in paragraph 0361 describes administration by inhalation which as already described is for treating lung

tumors and paragraph 364 describes the administration of antibodies and antigens mucosally. Line 8, page 41 is describing the route of infection of antigens i.e. mucosal surfaces such as oral, nasal, vaginal, penile and rectal and has nothing to do with a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract.

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Gerber et al., and Adams et al., one would still fall short of the of Applicants' claimed invention only to arrive at a method of treating lung cancer comprising a composition that includes an effective amount of a pain relieving and anti-inflammatory pharmaceutical where the route of infection of an antigen is mucosal surfaces such as oral, nasal, vaginal, penile and rectal.

Gerber et al. and Adams et al. alone or in combination do not teach or suggest all of the claim limitations of Claims as pending and, therefore, does not establish a *prima facie* case of obviousness (see MPEP 2143.03).

The combination of Gerber et al. and Adams et al. do not teach or suggest each and every element of Applicants' presently claimed invention i.e. method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives and thermoreversible polymers; from about .001% to about 20% by weight of a sensate; and wherein the composition has a viscosity of from about 1 cps to about 2000 cps.

Accordingly, Claims 1-5 and 8 – 10, and 12-15 are novel and nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Rejection Under 35 USC §103(a) Over Gerber et al. US 2001/0044410 in view of Adams et al. US 2004/0077601 in further view of Kamishita et al. US 5,158,761

Claims 6-8 and 10 have been rejected under 35 USC 103(a) as being unpatentable over Gerber et al. US 2001/0044410 in view of Adams et al. US 2004/0077601 in further view of Kamishita et al. US 5,158,761. The Examiner states that Kamishita et al. teaches a spray base gel composition comprising an aqueous solution of carboxyvinyl polymer with a water-soluble basic substance and a viscosity range of 500-5,000 cps. Additionally, the Examiner states that the pH is adjusted with a water-soluble substance such as sodium hydroxide or other pH adjustors. Applicants respectfully traverse this rejection based on the remarks contained herein.

Applicants assert that the arguments presented above regarding Gerber et al. US 2001/0044410 in view of Adams et al. US 2004/0077601 in traversing the § 103(a) rejection also apply to the present rejection.

Kamishita et al. discloses and requires the combination of a carboxyvinyl polymer with a water-soluble substance. Kamishita fails to teach or suggest about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives and thermoreversible polymers where the composition has a viscosity of from about 1 cps to about 2000 cps and where the cellulose derivative is selected from the group consisting of hydroxypropyl methylcelluloses, hydroxypropyl celluloses, methyl cellulose polymers, carboxymethyl cellulose polymers, salts of carboxymethyl cellulose. Additionally, Kamishita does not cure the lack of disclosure to a method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co).

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Gerber et al., Adams et al. and Kamishita et al, one would still fall short of the of Applicants' claimed invention only to arrive at a method of treating lung cancer comprising a composition that includes an effective amount of a pain relieving and anti-inflammatory pharmaceutical, 2-1.5% carboxyvinyl polymer, and a water-soluble substance, where the route of infection of an antigen is mucosal surfaces such as oral, nasal, vaginal, penile and rectal.

Gerber et al., Adams et al. and Kamishita et al, alone or in combination do not teach or suggest all of the claim limitations of Claims as pending and, therefore, does not establish a *prima facie* case of obviousness (see MPEP 2143.03).

The combination of Gerber et al., Adams et al. and Kamishita et al, do not teach or suggest each and every element of Applicants' presently claimed invention i.e. method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives and thermoreversible polymers; from about .001% to about 20% by weight of a sensate; and wherein the composition has a viscosity of from about 1 cps to about 2000 cps.

Accordingly, Claims 1-5 and 8 – 10, and 12-15 are novel and nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Rejection Under 35 USC §103(a) Over Gerber et al. US 2001/0044410 in view of Adams et al. US 2004/0077601 in further view of Kamishita et al. US 5,158,761 in further view of Betbeder et al. US 6,017,513

Claim 9 has been rejected under 35 USC 103(a) as being unpatentable over Gerber et al. US 2001/0044410 in view of Adams et al. US 2004/0077601 in view of Kamishita et al. US 5,158,761 and in further view of Betbeder et al. US 6,017,513. The Examiner states that Betbeder et al. teaches the use of an amphiphillic compound such as poloaxamers, modified polyoxyethylene for use in a nasal mucosal administration. Applicants respectfully traverse this rejection based on the remarks contained herein.

Applicants assert that the arguments presented above regarding Gerber et al. US 2001/0044410 in view of Adams et al. US 2004/0077601 further in view of Kamishita et al. US 5,158,761 in traversing the § 103(a) rejection also apply to the present rejection. Betbeber et al. discloses the use of amphiphilic compounds for coating an outer layer of the core partially or wholly. The amphiphilic compound preferably mainly comprises

natural or synthetic phospholipids or ceramide. The amphiphilic coating may also comprise poloxamers and modified polyoxyethylene. Betbeber et al does not teach or suggest a composition comprising from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives and thermoreversible polymers; wherein the mucoadhesive polymer is a thermoreversible polymer selected from the group consisting of poloxamers, ethylhydroxy ethylcelluloses, and mixtures thereof.

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Gerber et al., Adams et al. Kamishita et al., and Betbeder et al. one would still fall short of the of Applicants' claimed invention only to arrive at a method of treating lung cancer comprising a composition that is coated with an amphiphilic coating that may comprise poloxamers and modified polyoxyethylene, wherein the composition includes an effective amount of a pain relieving and anti-inflammatory pharmaceutical, 2-1.5% carboxyvinyl polymer, and a water-soluble substance, where the route of infection of an antigen is mucosal surfaces such as oral, nasal, vaginal, penile and rectal.

Gerber et al., Adams et al. Kamishita et al., and Betbeder et al. alone or in combination do not teach or suggest all of the claim limitations of Claims as pending and, therefore, does not establish a *prima facie* case of obviousness (see MPEP 2143.03).

The combination of Gerber et al., Adams et al., Kamishita et al., and Betbeder et al. do not teach or suggest each and every element of Applicants' presently claimed invention i.e. method of treating SARS by administering a nasal respiratory tract composition having a pH of from about 3.0 to about 5.5 to areas of the upper respiratory tract, wherein the respiratory tract composition comprises: from about 0.01% to about 10% by weight of an organic acid; from about 0.01% to about 20% by weight of a metal compound comprising a metal ion selected from the group consisting of manganese(Mg), silver (Ag), zinc (Zn), tin (Sn), iron (Fe), copper (Cu), aluminum (Al), nickel (Ni), cobalt (Co), or mixtures thereof; from about 0.01% to about 30% by weight of a mucoadhesive polymer selected from polymeric cellulose derivatives and thermoreversible polymers; from about .001% to about 20% by weight of a sensate; and wherein the composition has a viscosity of from about 1 cps to about 2000 cps.

Accordingly, Claims 1-5 and 8 – 10, and 12-15 are novel and nonobvious over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Conclusion

In light of the remarks and amendments presented herein, Applicants respectfully submit Claims 1-5 and 8 – 10, and 12-15are allowable over the cited reference. Reconsideration and allowance are respectfully requested. In the event that issues remain prior to allowance of the noted claims, then the Examiner is invited to call Applicant's undersigned attorney for further discussion.

Respectfully Submitted,

THE PROCTER & GAMBLE COMPANY

By _____
Cynthia L. Clay
Registration No. 54,930
(513) 622-0291

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Customer No. 27752